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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,287	05/30/2000	Yuhpyng L. Chen	U-014295-9	1655

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/580,287	CHEN, YUHPYNG L.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 SEP 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 45-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 45-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-15 and 45-52 are pending.

2. Claims 1-15 and 45-52 are rejected.

Response to Arguments

3. Applicant's arguments with respect to claim1-15, 45, and 46 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 47-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. *Regents of the University of California v. Eli Lilly & Co.., 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S.Ct. 1548 (1980),* holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the

claimed chemical invention." *Eli Lilly, 119 F.3d at 1566.* The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for *Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001)*, which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, "including, inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure...." *Enzo Biochem, Inc. v. Gen-Probe., 296 F.3d, 316, 1324-25 (Fed. Cir. 2002)* (quoting Guidelines, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp.2d 216, 225 (W.D.N.Y 2003).*

7. There is insufficient descriptive support for the phrases "combined with a second compound useful for treating a sleep disorder" or "combined with a second compound useful for treating emesis". In addition, the instant specification does not describe what is meant by the phrases "combined with a second compound useful for treating a sleep disorder" or "combined with a second compound useful for treating emesis." In addition, the instant specification fails to adequately teach and describe combined compositions of the corticotropin releasing factor antagonists of formula II along with any second compound let alone for the treatment of a sleep disorder or emesis. Structural identifying characteristics of the phrases "combined with a second compound

useful for treating a sleep disorder" or "combined with a second compound useful for treating emesis" are not disclosed. There is no evidence that there is any per se structure/function relationship between the phrases "combined with a second compound useful for treating a sleep disorder" or "combined with a second compound useful for treating emesis." The instant specification does provide an adequate written description for the term/phrase of phrases "combined with a second compound useful for treating a sleep disorder" or "combined with a second compound useful for treating emesis". Accordingly, these claims fail to comply with the written description requirement.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-15, 45, and 46-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The compound of formula II has incomplete valencey of the bridge head carbon atoms. In addition, the compound of formula II is missing a double bond or additional substituents located at the bridge head carbon atoms. Accordingly, this renders the claims vague and indefinite. Furthermore, the structure in the instant claims should be corrected to reflect the correct valence for the bridgehead carbon atoms, please see original claim 1 filed on May 30, 2000.

Obviousness-type Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claim 46 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,384,039. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instantly claimed subject matter and U.S. Patent No. 6,384,039 teach of the administration of the compounds of formula II, especially when the compound of U.S. Patent No. 6,384,039 has the dashed line in between variables E and D being equal to a single bond. In addition, both the instantly claimed subject matter and U.S. Patent No. 6,384,039 teach that the compounds of formula II are corticotropin releasing factor antagonists used in treating diseases (columns 7 and 8 for claim 1 of U.S. Patent No. 6,384,039) which is an obvious variation of terminology used in the current application claims of binding corticotropin in a patient to be treated. It is further expected that the diseases treated in the patent would have required binding of

corticotropin in the patient for the drug(s) to have had the appropriate reduction in incidence of the disease.

12. Claims 47-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,384,039 in view of Molloy et al. of U.S Patent No. 4,018,895. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instantly claimed subject matter and U.S. Patent No. 6,384,039 teach of the administration of the compounds of formula II, especially when the compound of U.S. Patent No. 6,384,039 has the dashed line in between variables E and D being equal to a single bond. In addition, both the instantly claimed subject matter and U.S. Patent No. 6,384,039 teach that the compounds of formula II are corticotropin releasing factor antagonists. In addition, both the instantly claimed subject matter and U.S. Patent No. 6,384,039 teach that the compounds of formula II are corticotropin releasing factor antagonists used in treating diseases (columns 7 and 8 for claim 1 of U.S. Patent No. 6,384,039) which is an obvious variation of terminology used in the current application claims of binding corticotropin in a patient to be treated. It is further expected that the diseases treated in the patent would have required binding of corticotropin in the patient for the drug(s) to have had the appropriate reduction in incidence of the disease. The prior art reference of Molloy et al. teach that depression is known to be treated with fluoxetine, see claims 1-2. Moreover, it would have been obvious to the skilled artisan that the administration of fluoxetine would also be useful to help an individual with sleep disorders because depressed individuals may possess sleeping disorders. "It is prima

facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

13. Claims 51 and 52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,384,039 in view of Bountra et al. . Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instantly claimed subject matter and U.S. Patent No. 6,384,039 teach of the administration of the compounds of formula II, especially when the compound of U.S. Patent No. 6,384,039 has the dashed line in between variables E and D being equal to a single bond. In addition, both the instantly claimed subject matter and U.S. Patent No. 6,384,039 teach that the compounds of formula II are corticotropin releasing factor antagonists. In addition, both the instantly claimed subject matter and U.S. Patent No. 6,384,039 teach that the compounds of formula II are corticotropin releasing factor antagonists used in treating diseases (columns 7 and 8 for claim 1 of U.S. Patent No. 6,384,039) which is an obvious variation of terminology used in the current application claims of binding corticotropin in a patient to be treated. It is further expected that the diseases treated in the patent would have required binding of corticotropin in the patient for the drug(s) to have had the appropriate reduction in incidence of the disease. The prior art reference of Bountra et al. disclose that GABA agonists are known in the art to be used for the

treatment of emesis, (see inter alia the abstract and from column 1, line 45 to column 2, line 5). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

14. Claim 46 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3; and 1 and 3; of copending Application No. 10/161,816 and 10/676,201, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application Nos. 10/161,816 and 10/676,201 teach of treating a condition with the administration of a corticotropin releasing factor antagonist. The skilled artisan would have been motivated to employ corticotropin releasing factor antagonist to treat an ailment.

15. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. In addition, this notice serves as an advisory to applicants to completely furnish information regarding related applications and granted patents that would impact patentability of this instant application. Applicant's did not call the attention of the Office to the above cited copending applicants and granted patent in the present application. Applicant's will not be permitted to extend the prosecution of the present application by reason of their inaction with regard to notice the Office of conflicting claims in copending

applications, the discovery of which necessitated the new grounds of rejection at this advanced point in prosecution. This situation is clearly analogous to the policy of making an action final where applicant's material amendments to the claims necessitated new ground of rejection, since in both instances it is applicant who caused the rejection to be applied after the case had received an action on the merits, see MPEP 706.07(a). In the event that an application is found which was not provided and disclosed to the Office, the following Office Action may be made Final.

Conclusion

17. Applicant's amendment, including the rejoinder of claims 46-52, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
December 27, 2004